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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
10/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,380	KHAN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 August 2007 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1, 13, and 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5, 7-10, 12-14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

In the specification and figures, Squitieri discloses the device substantially as claimed by applicant. With regard to claim 1, Squitieri discloses an arteriovenous shunt system comprising an arterial graft 53 with a lead end 19 anastomosed to an artery and terminal end connected to needle access site 20, which acts as a connector that corresponds to applicant's cuff. The system further comprises a venous outflow catheter 65 with an outflow end that is capable of being inserted through a vein into the right atrium of the heart (see FIGS 6-9) and an inflow end that is connected to access site 20 (see column 4). The access site 20, corresponding to applicant's cuff, directs passage

of blood from the arterial catheter to the venous catheter, and is in communication with the terminal end of the arterial graft and the inlet end of the venous catheter (see FIGS 6-9, column 5, lines 19-60). Squitieri further discloses that the arterial and venous catheters may be connected in various manners by cuffs that may comprise a cylindrical shape (see FIGS 2, 4, 6, 9, 11, 12, 14).

With regard to applicant's recitation of the diameters of the arterial and venous catheters in claims 1, 4, 5, 8, 9, 12, 14, and 18, Squitieri discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see column 3, line 60 to column 4, line 15). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). It appears that the device and method disclosed by Squitieri would perform in the same manner as claimed by applicant. Therefore, the sizes claimed by applicant are held by the examiner to be an obvious variation of the device and method disclosed by Squitieri.

Squitieri fails to disclose that the cuff or connector comprises a graded inside diameter to accommodate the various catheter diameters. However, such connectors that accommodate various diameter conduits are well known in the art of fluid handling, as demonstrated by Parks. Parks discloses a medical fluid handling apparatus with a ferrule or connector 70 that receives and joins different sized conduits with graded interior wall regions 82, 84, 86 (see FIG 7, column 4, lines 55-62). Therefore, it would

have been obvious to one having ordinary skill in the art at the time of invention to add a graded interior surface as disclosed by Parks to the connector between the arterial and venous catheters in the vascular access system disclosed by Squitieri in order to accommodate inserts of various diameters, as taught by Parks.

With regard to claims 2, 3, and 7, Squitieri discloses that in an embodiment, tubing or cuff 69 is made of PTFE (polytetrafluoroethylene), a biocompatible, flexible material (see FIG 8, column 5, lines 55-60).

With regard to claim 10, Squitieri discloses that in one embodiment, the venous catheter may comprise silicone tubing (see column 5, lines 25-29).

With regard to claim 13, Squitieri discloses that the arteriovenous graft system may be connected to a hemodialysis machine (not shown), meeting the limitations of the claim (see column 4, lines 60-64).

With regard to claim 17, Squitieri discloses that the graft may be surgically inserted (see column 7, lines 24-45), connected to a hemodialysis machine (which, by definition, purifies blood), collect blood through the arterial catheter, send the blood through a dialysis machine, and collect blood from the dialysis machine and return it to the patient via the venous catheter (see column 4, lines 50-64).

5. Claims 6, 11, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri and Parks disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of the particular arteries and veins that are used to connect to the arteriovenous system. Squitieri is silent as to the particular vessels used, but it is well-known in the art of arteriovenous grafts that one may select any given vessel based on the suitability for its purpose. Trerotola discloses a stent-graft that may be deployed between many vessels within a patient, and discloses a graft between a brachial artery and an axillary vein (see FIG 9A and accompanying text). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect the arteriovenous graft system disclosed by Squitieri to the brachial artery and axillary vein as disclosed by Trerotola in order to create blood flow between the selected vessels, as demonstrated by Trerotola.

Response to Arguments

6. Applicant's amendment and arguments and filed 21 August 2007 have been fully considered but they are not persuasive.

7. Applicant's arguments with respect to the 35 USC 102 rejections over Squitieri have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant argues that one skilled in the art would not be motivated to modify the needle access ports, quick couplings, and frames of the Squitieri device because it would not provide the exchangeability taught by Squitieri. However, Squitieri discloses several different methods of connecting the arterial and venous catheters (and discloses that the needle access 20 is not the only location a needle may pierce the access),

including a simple coupling as shown in FIG 4. Accordingly, one of ordinary skill in the art would, in fact, consider the nature of fluid couplings known in the art when contemplating the use of the Squitieri device.

9. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., depositing blood directly into the right atrium) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant merely claims the steps of providing a venous outflow catheter configured for insertion into the right atrium of the heart (claim 17, lines 8-9), and transmitting blood through the cuff into the venous outflow catheter (claim 17, line 24). The method does *not* comprise a step of depositing blood directly into the right atrium.

With regard to applicant's claim limitation drawn to the venous outflow catheter "configured for insertion through a vein into the right atrium of the heart," applicant fails to set forth any structural limitations that distinguish the claimed catheter from that disclosed by Squitieri. Squitieri even illustrates the venous outflow catheter inserted into the vena cava in the direction of the right atrium (see FIG 7). It is the position of the examiner that the venous outflow catheter disclosed by Squitieri is, without any structural modifications, capable of being deployed in a patient's right atrium, meeting the limitations of applicant's claim. Since Squitieri discloses and illustrates a catheter

that is capable of being deployed as claimed by applicant (see FIG 7), the disclosure meets the limitations of the claims.

10. In response to applicant's argument that the Squitieri reference and the Trerotola reference are not properly combined, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the Examiner is not suggesting that any of the portions of the devices disclosed by Squitieri and Parks be combined with the structure of the Trerotola device.

With regard to claims 19 and 20, Squitieri illustrates a connection between the axial artery and the right atrium via the jugular vein (see FIG 7), as well as a connection between the axial artery and the right atrium via the axial vein (see FIG 8), but fails to name the connected vessels. Examiner relied on Trerotola merely to provide a name for the artery 30 that Squitieri already discloses as being connected to the right atrium in FIG 7 and the vein 40 in which the venous catheter is inserted in FIG 8. Accordingly, the combination of the Squitieri and Trerotola references is proper, and the claims fail to overcome the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
24 October 2007